MAR 6 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. T. Michael Spencer
Manager, Regulatory Affairs
DEKALB Genetics Corporation
Discovery Research
62 Maritime Drive
Mystic, Connecticut 06355-1958

Dear Mr. Spencer:

This letter is in regard to your genetically modified corn line containing transformation event DBT418, about which you initiated consultation with the Agency on September 30, 1996. The new corn variety has been modified to confer resistance to lepidopteran insects through expression of the *cryIA(c)* gene from *Bacillus thuringiensis* subsp. *kurstaki*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new corn variety on September 30, 1996 and supplementary information on November 25, 1996. These communications were intended by DEKALB to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that DEKALB has concluded that corn grain and forage derived from the new variety is not materially different in composition, safety, or other relevant parameters from corn grain or forage currently on the market, and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF0040 and that will be maintained in the Office of Premarket Approval.

Based on the information DEKALB has presented to FDA, we have no further questions concerning corn containing transformation event DBT418 at this time. However, as you are aware, it is DEKALB's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,
/S/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:HFS-13, HFS-200, HFS-205, HFS-206, HFS-226, HFS-246, HFS-247, HFV-200, **BNF40**, HFV-2211, HFV-199, HFV-228